



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/750,409

12/30/2003

Johanna Jacoba Maria Meulenberg

2183-4041.4US

4880

28516

7590

08/15/2008

MICHAEL P. MORRIS

BOEHRINGER INGELHEIM USA CORPORATION

900 RIDGEBURY RD

P O BOX 368

RIDGEFIELD, CT 06877-0368

EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

08/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,409	Applicant(s) MEULENBERG ET AL.	
	Examiner MYRON G. HILL	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 34/21/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22 and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/08 has been entered.

This action is on claims 21, and 27-31.

Claim Objections Withdrawn

Claim 21 was objected to because of the following informalities: "SEQ ID# 18 its 5' end" appears to be a typo as compared to the other claims. "SEQ ID# 18 at its 5' end" is recited in the other claims. Applicant amended the claim.

Applicant was advised that should claim 21 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

Applicant has canceled claim 23.

Rejections Maintained/ Necessitated By Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 22, and 23-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite a PRRSV nucleic acid sequence comprising SEQ ID# 18 at its 5' end.

Applicant argues that the specification teaches that the 5 prime end is a prerequisite for the construction of infectious clones, and that the previously published sequence lacks the 5 prime end.

Applicant's arguments have been fully considered and not found persuasive.

The claims are not drawn to a method of making an infectious clone. As stated in the rejection, the claims are drawn to any PRRSV with SEQ ID# 18 at the end and applicant has only taught one "species". Applicant has not taught where to find additional members of the genus and applicant has not shown possession of sufficient members of the genus to have possession of the claimed genus.

New claims 27-29 and 31 add intended use limitations that do not show possession or where to find the virus that is only defined by 10 nucleotides.

The rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 and 30 are rejected under 35 U.S.C. 102(b) as anticipated by Wensvoort *et al.* (WO 92/21375).

Applicant argues that the reference does not teach SEQ ID# 18 and that applicant was the first to isolate such a molecule with SEQ ID# 18 at the end.

Applicant's arguments have been fully considered and not found persuasive.

Wensvoort *et al.* isolate the same virus and the viral genome contained therein is an infectious RNA molecule. The viral genome of Wensvoort *et al.* is full length and thus contains SEQ ID# 18 at the genome end.

New claim 30 adds an intended use limitation. The claim is drawn to an infectious RNA molecule, not a method of making a virus. The term "being expressed" is not an

active method step that requires a specific action. Thus, the limitation does not change the scope of the claim.

Thus, Wensvoort *et al.* clearly anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 22, and 23-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort *et al.* (WO 92/21375) and Moormann *et al.* (Journal of Virology 1996, Vol 70, pages 763-770).

Applicant argues that prior art would not result in the invention because it does not teach SEQ ID# 18 and one would not be able to use the methods of the claimed subject matter without the present invention. Additionally, applicant argues the Product by process limitations that the clones made [of the rejection] would not be able to be expressed in a host cell that is not capable of being infected.

Applicant's arguments have been fully considered and not found persuasive.

One of ordinary skill in the art at the time of invention would have cloned the virus to get a full length clone. Moormann *et al.* clearly teach the importance of having 3 and 5 prime ends (abstract, page 763, column 2 middle, and page 765, column 2 lower part). One of ordinary skill in the art at the time of invention would have cloned the virus

to get a full length clone using for example the strategy explained and shown in Figure 1 of Moormann *et al.* SEQ ID# 18 is part of the virus taught in Wensvoort *et al.* Applicant has not argued that it is not the same or that it is not there.

New claims 27-31 add intended use limitations. The term “being produced”, “being incapable”, “being capable of transfection”, and “being expressed” are not active method steps that requires a specific action. Thus, the limitation does not change the scope of the claim.

Thus, the claims are unpatentable over Wensvoort *et al.* and Moormann *et al.*

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on 5:30 am-2 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. H./

Examiner, Art Unit 1648

/A R Salimi/

Primary Examiner, Art Unit 1648